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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/123,253	07/27/1998	T. WILLIAM HUTCHENS	D-5639-C4	5339

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FULBRIGHT & JAWORSKI, LLP
1301 MCKINNEY
SUITE 5100
HOUSTON, TX 77010-3095

EXAMINER

ALEXANDER, LYLE

ART UNIT	PAPER NUMBER
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1743

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DATE MAILED: 02/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/123,253

Applicant(s)

HUTCHENS ET AL.

Examiner

Lyle A Alexander

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) 35, 51, 88 and 89 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims pending in the application are 49-53,56,57,60,61,63-71,75,76,82,87-91,94,95,104-113,120-127,130-141 and 144-148.

Continuation of Disposition of Claims: Claims rejected are 49,50,52,56,57,60,61,63-71,75,76,82,87,90,91,94,95,104-113,120-127,130-141 and 144-148.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 49-53,56-57,60-61,63-71,75-76,82,87-91,94-95,104-113,120-127,130-141,144-148 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitations "wherein the probe for sample holder has been added to all of the independent claims. This limitation is confusing and appears to contradict the invention. This limitation has been interpreted as meaning the sample collecting probe is not support by any other means. The instant invention requires the sample collecting probe to be supported as it is inserted and held in place in the mass spectrometer which apparently does not meet this claimed limitation because further probe support is required by the claimed invention. Further, it is not know what is intended by "not associated with a separate sample holder". What is a separate sample holder ?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 49, 64, 67-71, 86, 126-127 and 136 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Westlake et al. (USP 5,317,932).

The invention is best understood in light of the above 35 USC 112 issues, a single probe is used to collect the sample. Westlake et al. in column 2 lines 10-17 characterize Brodbelt et al. as teaching a mass spectrometric determination of in vivo analytes by use of a single nylon sample probe.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 49-50, 52, 56-57, 63-67, 69-71, 75-76, 82, 86-87, 90-91, 94-95, 101, 105-113, 120-127, 130-134, 137-141 and 144-148 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 3221681 (note the attached translation of the document).

As the invention is best understood in light of the above 35 USC 112 issues, a single probe is used to collect the sample. DE 3221681 teaches a method and apparatus for using a laser to desorb a biological sample from a polymer film further

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subjecting the desorbed sample on a single probe to subsequent mass spectrometry analysis.

DE 3221681 is silent to the type of polymer used and if the material is open or closed pore.

The court decided In re Leshin (125 USPQ 416) that mere selection of known plastic being on the basis of suitability for the intended use would be entirely obvious. The claimed polystyrene, polypropylene, polycarbonate, nylon and dextran as well as the porosity of these polymers are all well known polymeric materials in the art commonly used in biological assays because of inertness, light weight, high strength, low cost of manufacture and ease of disposal (e.g. all these materials can be readily incinerated). Open pores are advantageous better retain the sample while closed pores have the advantage of leaving more of the sample available to analysis.

It would have been within the skill of the art to modify DE 3221681 and use polymeric materials such as polystyrene, polypropylene, polycarbonate, nylon and dextran as well as selecting the relative porosity (e.g. open/closed pores) to gain the above advantages and as selection of a material based upon its suitability of intended use.

Claims 49, 64, 65-71, 80, 86, 126-127, 129 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cerami.

Cerami teaches in column 11 lines 48+ a mass spectrometry apparatus using a ceramic probe tip to present the sample.

Cerami is silent to the polymer used and if the material is open or closed pore.

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The court decided In re Leshin (125 USPQ 416) that mere selection of known plastic being on the basis of suitability for the intended use would be entirely obvious. The claimed polystyrene, polypropylene, polycarbonate, nylon and dextran as well as the porosity of these polymers are all well known polymeric materials in the art commonly used in biological assays because of inertness, light weight, high strength, low cost of manufacture and ease of disposal (e.g. all these materials can be readily incinerated). Open pores are advantageous better retain the sample while closed pores have the advantage of leaving more of the sample available to analysis.

It would have been within the skill of the art to modify Cerami and use polymeric materials such as polystyrene, polypropylene, polycarbonate, nylon and dextran as well as selecting the relative porosity (e.g. open/closed pores) to gain the above advantages and as selection of a material based upon its suitability of intended use.

Claims 50,52,56-57,60-61,63,75-76,82,87-91,94-95, 101,104-113,120-125, 130-134, 137-141 and 144-149 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cerami or Westlake et al. in view of Stuke (USP 4,686,366).

See Cerami and Westlake et al. supra.

Cerami and Westlake et al. are silent to the claimed use of laser desorption of the sample, the use of glass and their relative porosity (e.g. open/closed pore) of either the taught ceramic or glass.

Stuke teaches in column 1 lines 37+ that mass spectrometry analysis may fragment samples. It is advantageous to use a laser to desorb the sample to supply the mass spectrometer with large intact analytes.

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It would have been within the skill of the art to modify Cerami or Westlake et al. in view of Stuke and use a laser to desorb the samples to gain the above advantages.

The court decided In re Leshin (125 USPQ 416) that mere selection of known materials being on the basis of suitability for the intended use would be entirely obvious. Cerami teaches use of a ceramic material which is silicon based. It would have been within the skill of the art to use other well known silicon based materials such as glass. Glass as well as its relative porosity is a well known in the art as commonly used in biological assays because of inertness, light weight, high strength, low cost of manufacture and ease of disposal (e.g. all these materials can be readily incinerated). Open pores are advantageous better retain the sample while closed pores have the advantage of leaving more of the sample available to analysis.

It would have been within the skill of the art to modify Cerami or Westlake et al. in view of Stuke and use the claimed polymers as well as selecting the relative porosity (e.g. open/closed pores) to gain the above advantages and as selection of a material based upon its suitability of intended use.

Allowable Subject Matter

Claims 51,53,88 and 89 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

The cited prior art fails to teach a method of laser desorption mass spectrometry where the sample is further modified while on the probe.

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Response to Arguments

Applicant's arguments filed 11/3/03 have been fully considered but they are not persuasive.

Applicants argue "DE" does not insert the sample into the mass spectrometer. The Office maintains the art clearly teaches placement of the probe within the confines of the spectrometer permitting the samples access to spectrometric analysis. Applicants also state "DE" has the probe associated with a separate sample holder. In light of the above 35 USC 112 issues, the claims are best understood as teaching a single probe for supporting the sample in the mass spectrometer which has been clearly taught by "DE".

The remarks concerning Cottrell were convincing and this rejection has been dropped.

Applicants traverse the combination of Cerami in view of Stuke on the basis the combination of these two reference would still not meet the claimed limitations. The Office maintains Cerami teaches a sample on a probe that is placed within a mass spectrometer and Stuke teaches TOF and the associated advantages of TOF. The combination teaches the claimed limitations and has sufficient motivation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0651.



Lyle A Alexander
Primary Examiner
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